

AUG 29 1996

I.510(K) SUMMARY

Submitted By:

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COOK INCORPORATED
925 South Curry Pike
P.O. Box 489
Bloomington, IN 47402
(812) 339-2235
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Device:

Trade Name: Ventricular Catheter Set

Common/Usual Name: Ventricular Catheter, External
Drainage Catheter

Proposed Classification: Ventricular Catheter, External
Drainage Catheter
and Components
21 CFR 882.5550 (84JXG)

Predicate Devices:

The Ventricular Catheter Set is similar in terms of intended use, materials of construction, and technological characteristics to predicate ventricular catheters which have been reviewed as central nervous system fluid shunt devices.

Device Description:

The Ventricular Catheter Set is used to obtain access to a ventricular cavity of the brain to drain fluid externally for the purpose of relieving elevated intracranial pressure or fluid volume. The device is supplied sterile and is intended for one-time use. The materials comprising the device have an established history of use in medical product manufacturing.

Substantial Equivalence:

The device will be manufactured according to specified process controls and a Quality Assurance Program, undergoing packaging and sterilization procedures similar to devices currently manufactured and marketed by COOK INCORPORATED. This device is similar with respect to indications for use, materials and physical characteristics to predicate devices in terms of section 510(k) substantial equivalency.